

US EPA ARCHIVE DOCUMENT

OCSPP/OPP Anticipated Regulatory Development in FY 2011

Rule	Description	Rule Stage
<u>Agricultural Worker Protection Standard Revisions</u>	EPA is developing a proposal under FIFRA to revise the federal regulations guiding agricultural worker protection. The changes under consideration are intended to improve agricultural workers' ability to protect themselves from potential exposure to pesticides and pesticide residues. In addition, EPA is proposing to make adjustments to improve and clarify current requirements and facilitate enforcement. Other changes sought are to establish a right-to-know Hazard Communication program and make improvements to pesticide safety training, with improved worker safety the intended outcome. The potential need for change arose from EPA discussions with key stakeholders beginning in 1996 and continuing through 2004.	Proposed
<u>Certification of Pesticide Applicators</u>	EPA is proposing change the federal regulations under FIFRA that guide the certified pesticide applicator program. Change is sought to strengthen the regulations to better protect pesticide applicators and the public and the environment from harm due to pesticide exposure. The possible need for change arose from EPA discussions with key stakeholders. EPA has been in extensive discussions with stakeholders since 1997 when the Certification and Training Assessment Group (CTAG) was established. CTAG is a forum used by regulatory and academic stakeholders to discuss the current state of, and the need for improvements in, the national certified pesticide applicator program.	Proposed
<u>Reconsideration of Exemptions for Insect Repellents</u>	EPA is developing rulemaking to modify the minimum risk pesticides exemption under 40 CFR 152.25(f) to exclude personally applied insect repellents from the exemption and require an abbreviated data set for such products. EPA is taking this action because these pesticides claim to control pests of significant public health importance.	Proposed

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<u>Revisions to Minimum Risk Exemptions</u> (clarifications to exempted products)	EPA has determined that the current listing of active ingredients and references to inert ingredients in the Code of Federal Regulations should be made clearer to facilitate manufacturing processes, enforcement, and consumer choice among products. In this action, EPA will explore options for clarifying the active and inert ingredient listings, including both rule and non-rule actions.	Proposed
<u>Data Requirements for Product Performance</u>	EPA will propose to amend efficacy data requirements that specifically address the registration data needs of invertebrate pesticide product registrations as mandated by FIFRA. This rulemaking will provide clarity, consistency, and transparency. This proposal will seek to amend the current efficacy data requirements, which describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; and the maintenance of a pesticide registration.	Proposed
<u>Data Requirements for Antimicrobials</u>	EPA is updating and revising its pesticide data requirements for antimicrobial pesticide products. This action will revise the existing data requirements to reflect current regulatory and scientific standards. The data requirements will cover all scientific disciplines for antimicrobial pesticides, including product chemistry and residue chemistry, toxicology, and environmental fate and effects. In general, pesticide data requirements describe the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the maintenance of a pesticide registration; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.	Final
<u>Data Requirements for Plant-Incorporated Protectants (PIPs) and Certain Exemptions for PIPs</u> (SAN 5005)	EPA will propose codifying data requirements that specifically address the registration data needs of plant-incorporated protectants (PIPs). These data requirements would improve the Agency's ability to make regulatory decisions about the human health and environmental effects of PIPs. By codifying data requirements specific to PIPs, the regulated community would have a better	Proposed

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	understanding of and could better prepare for the PIP registration process. Also, EPA will propose to exempt cisgenic PIPs from registration to encourage research and development of useful biotechnology and reduce the number of PIPs seeking registration. Cisgenic PIPs are formed when genetic material is transferred, using bioengineering technology, between plants that could transfer the genetic material naturally.	
<u>Revision to Compliance Date for Pesticide Container/Containment Rule</u>	On June 15, 2010, EPA granted a 4-month extension of the compliance date by which the pesticide labels must be updated with the container management statements required by the pesticide container and containment regulations. At the same time, EPA proposed and sought public comment on a 1-year extension. While there has been significant progress in the number of pesticide labels that have been updated with the container management statements required by the container-containment regulations, EPA has recently become aware that there are still a substantial number of products whose labels must be submitted to EPA, reviewed and approved by EPA, and reviewed and approved by the States.	Completed
<u>Clarifying Changes to Labeling</u>	EPA is planning a rulemaking to make minor revisions to the labeling requirements for pesticides and devices. The purpose of this effort is to update the structure of the regulation and make several clarifying changes. In addition to these planned minor revisions, EPA will solicit suggestions from stakeholders on what the Agency might consider for future changes to the labeling regulations.	Proposed
<u>Revisions to EPA's Rule on Protections for Subjects in Human Research Involving Pesticides</u>	As part of a settlement agreement, EPA will propose revisions to broaden the applicability of its existing rule governing the protection of subjects in human research involving pesticides. In settling this litigation, EPA agreed to propose to apply the existing rule to research involving intentional exposure of a human subject to "a pesticide," without limitation as to the regulatory statutes under which the data might be submitted, considered, or relied upon. EPA also committed in the settlement agreement to propose amendments	Proposed

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	to the rule that would disallow consent by an authorized representative of a test subject, and that would require the Agency, in its reviews of covered human research, to document its ethics and science considerations in terms of the recommendations articulated in the National Research Council's 2004 report, Intentional Human Dosing Studies for EPA Regulatory Purposes.	
<u>Expansion of Crop Grouping Program</u>	EPA is revising the pesticide crop grouping regulations to create new crop groupings, add new subgroups, and expand existing crop groups by adding new commodities. The current crop groupings allow EPA to establish pesticide tolerances for multiple related crops based upon data for a representative set of crops. EPA expects these revisions to promote greater use of crop grouping for tolerance-setting purposes and to facilitate the availability of pesticides for minor crop uses.	Proposed
<u>Amendment of EPA's Regulatory Definition of Pests to Include Prion</u>	Through this action, EPA is considering expressly adding prions (proteinaceous infectious particles) to the list of pests in 40 CFR part 152, and requirements related to product performance (i.e., efficacy data), which is required for each antimicrobial end-use product for which public health related claims are made. As a result, a product intended to inactivate, destroy or mitigate prions on inanimate surfaces (i.e., "prion product") would be considered a pesticide and may be subject to registration under FIFRA. EPA believes that regulating prion products protects human health and the environment against unreasonable adverse effects and ensures that such products are effective.	Proposed
<u>Regulation to Clarify Labeling of Pesticides for Export</u>	EPA is developing this proposed rule to clarify, restructure, and add specificity to existing labeling regulations for the export of unregistered pesticide products and devices. EPA is also considering a minor new requirement for the labeling of unregistered pesticide products and devices shipped between establishments operated by the same producer to ensure that they are clearly marked as	Proposed

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	unregistered products intended for export in order to prevent them from inadvertently entering the U.S. market.	
<u>Minor Revisions to the Procedures to Ensure Protection of Data Submitters' Rights</u>	This action will address changes to procedures for the protection of exclusive use and data compensation rights of individuals and entities that submit data to the Agency in support of a pesticide registration decision (i.e., data submitters). The revisions are to accommodate statutory and procedural changes that have occurred over the last 25 years since issuance in 1984. The revisions would simplify the procedures, reduce burdens upon certain data submitters, and make minor changes to clarify the requirements.	Proposed
<u>Synchronizing the Expiration Dates of EPA Pesticide Applicator Certificates with the Underlying State or Tribal Applicator Certificate</u>	Applicators of restricted-use pesticides (RUP) can be certified by States, Tribes, or non-EPA Federal agencies that have an EPA-approved certification plan (authorized agencies). As part of a proposed Federal Plan, pesticide applicators may be issued an EPA certificate which allows them to apply RUPs in entities not covered by an authorized agency (e.g., parts of Indian Country) by submitting an application form and providing documentation of an existing valid certification issued by an authorized agency, without further demonstration of competency. Through this action, EPA will propose to synchronize the expiration dates so that the EPA certificate expires at the same time as the underlying state, tribal, or non-EPA federal certificate.	Proposed
<u>Microbial Pesticide Definitions and Applicability; Clarification and Availability of New Test Guideline</u>	As promulgated, EPA's regulations distinguish "isolates" and "strains" in a confusing and non-obvious manner. This has resulted in significant uncertainty within the regulated industry. This proposed rule addresses this problem by proposing new regulatory language that clarifies the requirements applicable to new strains that are considered to be new active ingredients under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA is also announcing the availability of a new microbial pesticide test guideline, explaining the deposition of a sample in a nationally recognized culture collection data requirement, for comment. The	Proposed

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	revisions proposed in this rule also include several other minor corrections to words and references. The changes should enhance the ability of industry to efficiently manage their microbial pesticide registration submissions.	
<u>Public Availability of Identities of Inert Ingredients in Pesticides</u>	In response to two petitions under the Administrative Procedures Act seeking disclosure of selected inert ingredients on pesticide labels (based on the hazard of that ingredient), EPA is contemplating rulemaking to increase public availability of both potentially hazardous inert ingredients and of inert ingredient identities in general. This action would assist consumers and users of pesticides in making informed decisions and reduce the presence of potentially hazardous ingredients in pesticides. EPA is considering various approaches, including disclosure based on hazard and broader disclosure of inert ingredient identities.	Advance Notice Completed
<u>Electronic Reporting of Chemical and Pesticides Import Data in the Automated Commercial Environment (ACE)</u>	EPA will consult with Customs and Border Protection (CBP), in the Department of Homeland Security, to propose regulatory revisions necessary for the implementation of electronic reporting of chemical and pesticides import information in the Automated Commercial Environment (ACE). ACE is a data warehouse being designed by CBP that will serve as a single portal for the electronic collection and processing of all data required by any federal agency pertaining to the importation of commodities into, and their exportation from, the U.S. For EPA, this includes amendments to related regulations under the Toxics Substances Control Act (TSCA) and FIFRA, which impose reporting requirements for importers and exporters of chemical substances and pesticides.	Proposed